

### Remarks

Claims 19, 21-32, 34-36 and 42 are being examined on the merits. Claims 1-18 and 20 were previously canceled without prejudice. Claims 33 and 37-41 have been withdrawn by the Examiner. Claims 19, 31, 34 and 42 have been amended. Amendments do not introduce new matter and are provided to further define Applicants' claimed invention.

On pages 2-3 of the Office Action mailed December 2, 2008, the Examiner rejected the claims under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants have amended Claims 19 and 31 and have removed the term "substantially," a term regarded by the Examiner as being unclear. Claim 42 has been amended to remove the term "shape" regarded by the Examiner as being ambiguous. The independent claims have also been amended to disclose the claims in better form. No new matter has been introduced that would require an additional search on the part of the Examiner. Entry and allowance of the amended claims is respectfully requested.

On pages 4 and 5 of the Office Action, the Examiner provisionally rejected the claims under 35 U.S.C. 101 as claiming the same invention as that of co-pending U.S. Patent Application No. 11/648,384. Applicants respectfully traverse the rejection and submit that the rejection is not proper, pointing out that 35 U.S.C. 101 specifically recites, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." Under the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility as set forth by the U.S. Patent and Trademark Office, an application and its claims are said to meet the requirements under 35 U.S.C. 101 if the claimed invention as a whole is "useful and accomplishes a practical application." Applicants respectfully submit that such criteria are met by the claims because; for example, claims are directed to an artificial intervertebral disc, which is considered to be useful and accomplishes a practical application. Accordingly, Applicants submit that the claims of the present application are considered new and useful or a new and useful improvement thereof. Furthermore, the claimed subject matter does not fall outside all of the statutory categories. If such is the case, the Examiner must provide a *prima facie* case of unpatentability and must provide an explanation,

which the Examiner has not done. Hence, the claims meet all of the requirements of 35 U.S.C. 101. The rejection under 35 U.S.C. 101 should be removed.

On page 6 of the Office Action, the Examiner provisionally rejected the claims on the ground of nonstatutory obviousness-type double (ODP) patenting as being unpatentable over claims 19-36 of co-pending Application No. 11/648,384. Applicants respectfully traverse the rejection on the grounds that the claims are not obvious and further request the rejection be held in abeyance until there is allowable subject matter. In addition, Applicants note that if there are two co-pending applications, the first to receive allowable subject matter should have the ODP rejection removed and be allowed to proceed to issuance.

On pages 6-7 of the Office Action, the Examiner rejected Claims 19, 21-32, 34-36 and 42 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,602,292 (hereinafter, "Burkinshaw"). On page 2 of the Office Action, the Examiner stated that Burkinshaw "is sized and configured and fully capable of being used in the disc," further stating that Burkinshaw teaches all the structural limitations of Applicants' claimed invention. Applicants respectfully disagree and refer the Examiner to the amended claims set. Burkinshaw does not teach each and every element of Applicants' claimed invention. For example, Burkinshaw specifically teaches a patellar prosthesis and does not teach nor does the reference even suggest an artificial intervertebral disc. The patellar device is made of three parts, that for operation must also act via a "coupling component" in order to provide at least two types of articulation, including: (a) articulation with a first articulating surface (e.g., articulating surface 44); and (b) articulation with a second articulating surface (e.g., sliding contact between plate structure 60 having slide surface 64 and base component 34). Thus, Burkinshaw does not teach a single articulating surface. In fact, Burkinshaw explicitly states that the patellar prosthesis operates to require not only an articulation with the articulating surface 44, it also operates and requires "medial-lateral movement of articulation component 32 [with reference to the base] during reconstruction and use of the knee joint" (Col. 5, ll. 26-28). In addition, the multi-component device of Burkinshaw, which unlike Applicants amended claims, includes more than one component in which an articulating surface of the first component is not fixed with reference to a second surface that is adapted for fixation to bone. For example, Burkinshaw specifically requires

several components: the first is an articulation component 32, which is really two parts, in which the first part is defined by a first articulating surface 44 and at least a second interior surface 46 and the second (patella insert 42) is defined by a plate structure 60 having an interior surface 62 and at least a second articulating surface 64. The last component of Burkinshaw is a base component 34 defined by a bearing slide surface 78 and a fixation surface 72. The articulation component includes two articulating surface and no portion of it allows for the fixation to bone. The base component includes at least one articulating surface and a portion for fixation to bone. Thus, with Burkinshaw, the slide surface (78) of the base component articulates with the sliding surface (64) of the articulation component. Yet the base component does not have an articulating surface that is a hyperbolic paraboloid. As such, not only is there not a single articulating surface as defined by Burkinshaw, there is no single articulating surface that is a hyperbolic paraboloid and fixed relative its second surface that is adapted for fixation to bone. Accordingly, and contrary to the Examiner's statement, Burkinshaw does not teach each and every element of the claimed invention nor all the structural limitations of the claim.

On page 7 of the Office Action, the Examiner rejected Claims 19, 21-23, 25, 28-32, 34-36 and 42 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,872,519 (hereinafter, "Giannestras"). On page 2 of the Office Action, the Examiner stated that he interprets the entire articulating surface as a single surface. The Examiner also stated on page 2 that Giannestras describes "the shape collectively as a single shape." Applicants respectfully submit that Giannestras does not teach each and every element of Applicants' claimed invention as amended with this paper, which clarifies the articulating surface with removal of the term "substantially" considered indefinite by the Examiner. For example, Giannestras specifically teaches a total ankle prosthesis and does not teach nor does the reference even remotely suggest an artificial intervertebral disc. The total ankle device of Giannestras is, like Burkinshaw, made of at least two parts, that for operation also requires more than one articulating surface. A first articulating surface is the bearing surface of the talar member and the second articulating surface is a bearing surface of the tibial member. The combined parts permit the talar member to move relative to the tibial member. Furthermore, the articulating surface of the talar member is a composite of several shapes, defined specifically by Giannestras (and as pointed out by the Examiner) as a "single groove, double-ridged surface" (Col. 4, ll. 17-20). Specifically, the bearing surface 44 of

the talar member is defined as including arcuate channel 70 flanked by wing portions 72 (Col. 4, ll. 1-3; illustrated in FIGS. 1-3). One skilled in the art will readily see that wing portions 72 are convex surface regions and are not shaped as a hyperbolic paraboloid. Similarly, the articulating surface of the tibial member is a composite of several shapes, defined specifically by Giannestras (and as pointed out by the Examiner) as a “single-ridge, double grooved surface” (Col. 4, ll. 20-22). Specifically, bearing surface 26 of the tibial member is defined as including central depending rib 80 and wing portions 82 (Col. 4, ll. 20-22; illustrated in FIGS. 1-3). Wing portions 82 are clearly (particularly to one skilled in the art) concave surface regions and such a shape is not a hyperbolic paraboloid. Thus, Giannestras does not teach a single articulating surface or a single articulating surface that is a hyperbolic paraboloid shape. Accordingly, Giannestras does not teach each and every element of the claimed invention nor all the structural limitations of the claim.

On pages 8-9 of the Office Action, the Examiner rejected Claims 19, 21-32, 34-36 and 42 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,039,763 (hereinafter, “Shelekov”). On page 2 of the Office Action, the Examiner stated Shelekov teaches “the articulating surfaces (3, 12) can be regularly or irregularly shaped as at least partially complementary portions of spheroids, paraboloids, hyperboloids or ellipsoids of revolution or combinations thereof.” The Examiner further interprets surface 3 as a single articulating surface. Applicants respectfully submit that Shelekov does not teach each and every element of Applicants’ claimed invention as amended with this paper, which clarifies the articulating surface with removal of the term “substantially” considered indefinite by the Examiner. For example, Shelekov specifically teaches a device that is, in design, explicitly stated to operate and to articulate like a human knee. The human knee, like Shelekov’s device, has more than one articulating surface. Thus, Shelekov does not teach a single articulating surface. Shelekov explicitly states that its device requires a first plate (1) and a second plate (10). Each plate (1 and 10) has an articulating surface (3 and 12) and each articulating surface is also not a hyperbolic paraboloid. In fact, Shelekov specifically describes said surfaces as resembling condyles of the knee (Col. 6, ll. 1-21), which are known to one skilled in the art as not being a hyperbolic paraboloid. Furthermore, Shelekov explicitly states that condyles (4, 5) of plate 1 are convex and modes (13, 14) of plate 10 are concave (Col. 6, ll. 10-20; Col. 6, ll. 33-44). As such,

Shelekov does not teach a single articulating surface or a single articulating surface that is a hyperbolic paraboloid shape. Accordingly, Shelekov does not teach each and every element of the claimed invention nor all the structural limitations of the claim.

Applicants respectfully request the rejections relying on Burkinshaw, Giannestras and Shelekov each submitted under 35 U.S.C 102(b) be removed and the application be allowed to proceed to allowance.

### **Conclusion**

In light of the amendments and remarks presented with this paper, Applicants respectfully submit amendments to the claims as provided in the Listing of Claims beginning on page 3 of this paper. Applicants further submit such claims introduce no new matter and are believed to place the Application in condition for allowance.

This paper is being filed concurrently with a Request for Continued Examination, a request for an extension of time and the appropriate fees. Should any additional fees be due, Applicants herewith authorize the Commissioner to charge any additional fees, other than the issue fee, that may be required by this paper to Deposit Account 07-0153. Any overpayments should be deposited to the same deposit account.

Should the Examiner have any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

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Respectfully submitted,

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